09-25-03

16467

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicants:	Etcheverry et al.	Docket No:	21657-0002C-1
Serial No:	09/705,285	Group Art Unit:	1646
Filed:	November 1, 2000	Examiner:	Pak, Michael, D.
For:	**MAMMALIAN CELL CULTURE PROCESS**		

Box Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

☒ Transmitted herewith are the following documents for the above-referenced application:

☒ Response to Office Action.

STATUS

☒ Applicant is

☐ a small entity

☒ other than a small entity.

EXTENSION OF TIME

☒ Applicant petitions for an extension of time under 37 CFR 1.136 for the total number of months checked below:

	Extension (months)	Fee for other than small entity	Fee for small entity
☐	one month	$ 110.00	$ 55.00
☐	two months	$ 410.00	$205.00
☒	three months	$ 930.00	$465.00
☐	four months	$1,445.00	$725.00

Fee **$930.00**

CERTIFICATE OF MAILING (37 CFR 1.10(a))

CERTIFICATE OF MAILING BY "EXPRESS MAIL" - Rule 10: I hereby certify that this correspondence is being deposited on September 23, 2003 with the U.S. Postal Service "Express Mail Post Office to Addressee" under 37 CFR 1.10 as **Express Mail No. EV346725675US** addressed to: Mail Stop: Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: September 23, 2003

Cheryl Ann Rogers

FEE FOR CLAIMS

☐ If an additional extension of time is required please consider this a petition therefor.

☐ An extension for _____ months has already been secured and the fee paid therefor of $_____ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request $____

☐ The fee for claims (37 CFR 1.16(b)-(d)) has been calculated as shown below:

(Col. 1)		(Col. 2)		(Col. 3)	SMALL ENTITY		*OR*	OTHER THAN A SMALL ENTITY	
Claims Remaining After Amendment		Highest No. Previously Paid For		Present Extra	Rate	Addit. Fee		Rate	Addit. Fee
Total *	Minus *0*	20	=	0	x9=	$		x18=	$
Indep. *	Minus *0*	3	=		x40=	$		x80=	$
☐ FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					+130=	$		x260=	$
					TOTAL ADDIT. FEE	$	*OR*	TOTAL ADDIT. FEE	$

☒ No additional fee for claims required.
☐ Total additional fee for claims required $_____.

FEE PAYMENT

☒ Attached is a check in the sum of **$930.00** for the three-month extension of time.
☐ Charge Account No. 08-1641 the sum of $_____ for publication fee.

FEE DEFICIENCY

☒ In the event that: a) no check to cover the filing fee is enclosed, b) any above-referenced check is inadvertently omitted or lost, or c) any enclosed check is in an amount less than or greater than the required fee, the Commissioner is authorized to charge any required fees, additional fees, or credit any overpayment to Deposit Account 08-1641.

☒ Attached is a postcard for date-stamped return as confirmation of receipt of these materials.

Date: September 23, 2003

Ginger R. Dreger
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RESPONSE TO OFFICE ACTION

Mail Stop: Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed on March 24, 2003 in connection with the above-identified patent application, please consider the following arguments. The present response is accompanied by a request for a three months extension of time and the requisite fee, and is therefore timely filed.

Telephone Interview

Applicants thank the Examiner for the opportunity to discuss the double patenting rejections during a telephone interview on September 22, 2003 between the Examiner and the undersigned attorney. Applicants pointed out that U.S. Patent No. 5,510,261 names inventors different from the inventors of the present application, and is assigned to a different assignee, therefore, its citation in an obviousness-type double patenting rejection is improper. The Examiner confirmed that the '261 patent was erroneously cited in lieu of U.S. Patent No. 5,721,121. In the following arguments, Applicants will address the '121 patent as basis for one of the two obviousness-type double patenting rejections.

CERTIFICATE OF MAILING (37 CFR 1.10(a))

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Date: September 23, 2003

Cheryl Ann Rogers

Arguments

Claims 24-27 are pending in this application, of which claims 24-26 are under examination, while claim 27 has been withdrawn from consideration as being drawn to a non-elected invention.

Claims 24-26 have been rejected under the judicially created doctrine of obviousness-type double patenting "as being unpatentable" over claims 1-13 of U.S. Patent No. 5,510,261 and claims 1-21 of U.S. Patent No. 5,705,364, respectively. As noted above, Applicants will substitute U.S. Patent No. 5,721,121 for U.S. Patent No. 5,510,261 when addressing these rejections.

The rejections are respectfully traversed.

Legal Standard

An obviousness-type double patenting rejection prevents applicants from extending their patent term beyond statutory limits where an application claims merely an obvious variation of the claims in an earlier patent. In re Goodman, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993). The Federal Circuit established two tests for assessing obviousness-type double patenting. Under the "one-way" test, the court examines whether the claims in the pending application are patentably distinct from the claims of the issued patent. Goodman Id. 1053-54. Under the "two-way test" both the claims of the pending application and the claims of the issued patent are examined for patentable distinctiveness over each other, rather than merely determining if the claims of the pending application are obvious over the issued claims. In re Braat, 937 F.2d 589, 593, 19 USPQ2d 1289, 1292 (Fed Cir. 1991). If applicants had significant control over the rate of prosecution of their applications, the one-way test is obviousness analysis is properly applied. In re Emert, 124 F.3d 1458, 44 USPQ2d 1149 (Fed. Cir. 1997).

Claims 24-26 of the present application are not obvious over claims 1-8 of U.S. Patent No. 5,721,121.

The claims under examination in the present application (claims 24-26) concern a method for culturing a mammalian host cell to produce a heterologous glycoprotein, in which the in the growth phase the cell is cultured at a temperature suitable for cell growth, while in the subsequent production phase culturing is performed at a temperature lower than the temperature of the growth phase.

Claim 1 of the '121 patent concerns a process for producing a human TNFR1-IgG_1 chimetic protein comprising: (a) culturing a CHO host cell which expresses a human TNFR1-IgG_1 chimera in a growth phase at a temperature near 37.°C. under such conditions and for a period of time such that maximum cell growth is achieved; (b) culturing the host cell in a production phase: (1) in the presence of sodium butyrate at a concentration of about 6 mM to about 12 mM; (2) while maintaining the osmolality at about 450-600 mOsm; and (3) while maintaining the temperature about between 30.°C. and 35.°C.

Claim 1 of the '121 patent, in addition to the temperature ranges for performing the growth and the production phases, recites a number of parameters, including the type of the host cell (CHO cell), the presence of sodium butyrate at a given concentration, and a certain osmolality range. Additionally, the issued claim is specific to TNFR-IgG_1 chimera. In view of this, it would not have been obvious for one skilled in the art to design a process, which is applicable to all heterologous proteins, and which is characterized solely by the fact that the production phase is performed at a temperature lower than the temperature of the growth phase. The same analysis is true for the other independent claim, claim 4, as well as claims dependent on claim 1 and claim 4, respectively.

Accordingly, the obviousness-type double patenting rejection is believed to be misplaced, and should be withdrawn.

Claims 24-26 of the present application are not obvious over claims 1-21 of U.S. Patent No. 5,705,364.

Claims 24-26 of the present application are as discussed above.

Claim 1 of the '364 patent concerns a process for controlling the amount of sialic acid on an oligosaccharide side-chain of a glycoprotein, by adding alcanoic acid in a certain concentration range, keeping the osmolality within a certain range, and maintaining the temperature (production phase) within about 30 °C and 25 °C. This claim does not even mention the temperature of the growth phase, nor do the dependent claims. Accordingly, one skilled in the art would not have found it obvious to use a process which is characterized solely by the fact that the production phase is performed at a temperature lower than the temperature of the growth phase.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 21657-0002C-1). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: September 23, 2003

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